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Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' MOTION AND
MEMORANDUM IN SUPPORT OF
MOTION FOR SUMMARY
JUDGMENT AS TO PLAINTIFF
CAROL KRUSE'S CLAIMS**

CAROL KRUSE, an individual,

(Assigned to the Honorable David G.
Campbell)

Plaintiff,

(Oral Argument Requested)

v.

C. R. BARD, INC., a New Jersey
corporation and BARD PERIPHERAL
VASCULAR, INC., an Arizona
corporation,

Defendants.

MOTION

Pursuant to Fed. R. Civ. P. 56, Local Rule 56.1, and Case Management Order No. 23 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively “Bard”) respectfully move this Court for summary judgment as to Plaintiff Carol Kruse’s product liability claims (Counts II, VI, VII, VIII, IX, XII, XIII, XIV¹) and her claim for punitive damages as alleged in the Master Complaint.² For the reasons stated below, Bard is entitled to judgment as a matter of law.

This motion is supported by Defendants’ Memorandum of Points and Authorities and Separate Statement of Facts (“SSOF”) which are filed herewith.

MEMORANDUM OF POINTS AND AUTHORITIES

I. Introduction.

Plaintiff Carol Kruse brings this product liability action for damages she claims to have suffered as a result of complications allegedly experienced related to a Bard G2® inferior vena cava (“IVC”) filter, a prescription medical device that is designed to prevent potentially fatal pulmonary emboli. Before Ms. Kruse received her IVC filter, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (the “Filter”).

Plaintiff claims that her Filter is defective because, after placement, it allegedly migrated, perforated, fractured, and tilted, and she underwent an unsuccessful percutaneous procedure to have the device removed. Although Plaintiff first learned of her

¹ The parties met and conferred regarding Plaintiff’s claims. Plaintiff agreed she is not pursuing claims for manufacturing defect (Counts I, V), breach of express warranty (Count X), breach of implied warranty (Count XI), loss of consortium (Count XV), wrongful death (Count XVI), or survival (Count XVII). However, Plaintiff represented that she intends to pursue all of the claims addressed in this Motion.

² Plaintiff filed her original complaint on April 6, 2015, in the District Court for the District of Nebraska. Pursuant to Case Management Order No. 4, the Master Complaint is deemed pled in Plaintiff’s case. (See Dkt. No. 363.)

1 alleged injuries in or before March 2011, she waited more than four years (during which
2 time she requested and obtained a bankruptcy discharge) to file her claims against Bard.

3 Plaintiff's Filter remains implanted in Ms. Kruse. Notably, the potential for Ms.
4 Kruse's G2 Filter to migrate, perforate, tilt, fracture, and be unable to be retrieved are
5 risks that are well-known and accepted potential complications associated with all
6 retrievable IVC filters, and they are risks that Bard specifically warned about in the
7 Instructions for Use ("IFU") that accompanied Ms. Kruse's Filter. Moreover, Plaintiff's
8 implanting physician, Dr. Shanon Smith, testified that before he placed the G2 Filter in
9 Ms. Kruse, he was aware of the potential complications associated with use of the device,
10 including the risks of tilt, migration, perforation, and fracture.

11 Bard moves for summary judgment under Rule 56 on the following grounds:

12 A. Plaintiff's claims are barred by Nebraska's 4-year statute of limitations.

13 B. Plaintiff's claims are barred by the doctrine of judicial estoppel.

14 C. Plaintiff's failure-to-warn claims (Counts II, VII) fail as a matter of law because
15 Bard provided legally adequate warnings to a learned intermediary (Plaintiff's
16 implanting physician), and any alleged failure to warn by Bard was not the
17 proximate cause of Plaintiff's alleged injuries.

18 D. Plaintiff's negligent post-sale duty to warn claim (Count VI) fails as a matter of
19 law because Nebraska does not recognize a post-sale duty to warn.

20 E. Plaintiff's negligence per se claim (Count IX) fails as a matter of law because
21 such a claim cannot be based on alleged violations of a statute or regulation.

22 F. Plaintiff's negligent and fraudulent misrepresentation/concealment claims
23 (Counts VIII, XII, XIII) fail as a matter of law because there is no proof that
24 Plaintiff or her implanting physician relied on an alleged misrepresentation or
25 omission of material fact by Bard regarding the Filter.

26 G. Plaintiff's consumer fraud claim (Count XIV) fails as a matter of law because
27 the relevant statute awards injunctive relief, not money damages, and because
28 the relevant statute applies only to claims based on alleged losses of business or

property, not personal injury claims.

H. Plaintiff's claim for punitive damages fails as a matter of law because Nebraska does not permit recovery of punitive damages in a civil case.

II. Statement of Undisputed Facts.

Plaintiff Carol Kruse received a Bard G2 Filter on July 8, 2009. (SSOF, ¶ 1.) The Filter is a prescription medical device not available to the general public. (*Id.* at ¶ 2.) Ms. Kruse received her Filter [REDACTED]

[REDACTED] (*Id.* at ¶ 3.) According to Plaintiff's implanting physician, Dr. Smith, Ms. Kruse [REDACTED]

[REDACTED] (*Id.* at ¶ 5.)

Dr. Smith testified that before he placed the Filter, he had the IFU available to him to read. (*Id.* at ¶ 17.) The relevant IFU contains specific warnings regarding the risks of filter tilt, migration, fracture, perforation, and inability to retrieve, which are complications allegedly experienced by Ms. Kruse. (*Id.* at ¶¶ 18, 19.) Dr. Smith testified that he was independently aware of the risks of filter tilt, migration, perforation, and fracture, and that he would have discussed with Ms. Kruse the potential complications associated with her receiving an IVC filter. (*Id.* at ¶ 20.) Notably, complications such as tilt, migration, perforation, fracture, and inability to retrieve are complications associated with all brands of retrievable IVC filters, not just Bard's IVC filters.

Ms. Kruse testified that, [REDACTED]
[REDACTED].
(*Id.* at ¶ 6.) She also testified that in approximately late 2010, [REDACTED]
[REDACTED]

1 [REDACTED] (*Id.* at ¶ 7.) Additionally, in 2009 or
 2 2010, Ms. Kruse saw TV advertisements soliciting potential IVC filter plaintiffs. (*Id.* at ¶
 3 8.) Ms. Kruse testified that she saw these advertisements before she underwent her Filter
 4 removal procedure in April 2011. (*Id.* at ¶ 9.) Within “a couple of weeks” of seeing the
 5 TV advertisements, Ms. Kruse called the phone number she saw on the advertisement
 6 regarding her potential IVC filter claim. (*Id.* at ¶ 10.) Although it was “years” before she
 7 formally hired an attorney regarding her potential IVC filter lawsuit, Ms. Kruse testified
 8 that she periodically received letters regarding her “case” from a lawyer named Russell
 9 Button.³ (*Id.* at ¶ 11.) Ms. Kruse also testified that she called her daughter shortly after
 10 seeing the TV advertisements regarding potential IVC filter lawsuits to discuss her Filter.
 11 (*Id.* at ¶ 12.) On March 14, 2011, [REDACTED]
 12 [REDACTED]. (*Id.* at ¶ 13.) [REDACTED]
 13 [REDACTED]
 14 [REDACTED] (*Id.* at ¶ 15.) [REDACTED]
 15 [REDACTED]
 16 [REDACTED] (*Id.* at ¶ 14.)

17 On April 7, 2011, Ms. Kruse underwent an unsuccessful percutaneous filter
 18 removal procedure. (*Id.* at ¶ 27.) Ms. Kruse admits that at least as of April 7, 2011, she
 19 first attributed symptoms to her Bard G2 Filter. (*Id.* at ¶ 16.) Dr. Smith attempted the
 20 removal procedure, but he was unable to retrieve the filter because it was tilted with the
 21 tip of the filter abutting Ms. Kruse’s IVC wall. (*Id.* at ¶ 28.) However, Plaintiff’s own
 22 vascular and interventional radiologist expert, Dr. Darren Hurst, testified that Ms. Kruse’s
 23 Filter could “likely” be removed via a complex percutaneous procedure. (*Id.* at ¶ 29.)

24 On February 5, 2013, Ms. Kruse filed a Chapter 7 Bankruptcy Petition. (*Id.* at ¶
 25 30.) In her Petition, Ms. Kruse filled out a Schedule in which she verified all of her
 26 “personal property . . . of whatever kind.” (*Id.* at ¶ 31.) Under No. 21 “Other contingent
 27

28 ³ Mr. Button is a former associate of Plaintiff’s current lawyers.

1 and unliquidated claims of every nature,” Ms. Kruse marked an “X” for “NONE.” (*Id.* at ¶
 2 32.) Likewise, under No. 35 “Other personal property of any kind not already listed,” Ms.
 3 Kruse marked an “X” for “NONE.” (*Id.* at ¶ 33.) Ms. Kruse also filled out a Schedule in
 4 which she identified \$36,067.44 in creditor’s unsecured, nonpriority claims. (*Id.* at ¶ 34.)
 5 Ms. Kruse signed the Petition, declaring under penalty of perjury that the information
 6 provided in the Petition is true and correct. (*Id.* at ¶ 35.)

7 On February 8, 2013, an Interim Trustee was appointed to Ms. Kruse’s bankruptcy
 8 estate. (*Id.* at ¶ 36.) On April 1, 2013, after making a “diligent inquiry into the financial
 9 affairs” of Ms. Kruse, the trustee declared that he did not “receive[] any property” for the
 10 estate, and that “there is no property available for distribution,” and he certified that Ms.
 11 Kruse’s estate has been fully administered. (*Id.* at ¶ 37.) On June 3, 2013, Ms. Kruse
 12 obtained a bankruptcy discharge order. (*Id.* at ¶ 38.)

13 **III. Summary Judgment Standard.**

14 Summary judgment is appropriate when “there is no genuine dispute as to any
 15 material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P.
 16 56(a). “A moving party without the ultimate burden of persuasion at trial . . . has both the
 17 initial burden of production and the ultimate burden of persuasion on a motion for
 18 summary judgment.” *Nissan Fire & Marine Ins. Co. v. Fritz Cos.*, 210 F.3d 1099, 1102
 19 (9th Cir. 2000). “In order to carry its burden of production, the moving party must either
 20 produce evidence negating an essential element of the nonmoving party’s claim or defense
 21 or show that the nonmoving party does not have enough evidence of an essential element
 22 to carry its ultimate burden of persuasion at trial.” *Id.* “If . . . a moving party carries its
 23 burden of production, the nonmoving party must produce evidence to support its claim or
 24 defense.” *Id.* at 1130-31 (internal citations omitted).

25 **IV. Argument and Citation of Authority.**

26 **A. Plaintiff’s Claims Are Barred by Nebraska’s Statute of Limitations.**

27 Plaintiff subjectively knew about her alleged Filter injury at least as early as March
 28 14, 2011, which is the date she underwent pre-operative clearance to have her Filter

1 removed. (SSOF, ¶¶ 13, 14, 15.) Yet, Plaintiff waited more than 4-years until April 6,
2 2015, to file her Complaint. Plaintiff's claims are time-barred.

3 Nebraska has a 4-year statute of limitations for personal injury product liability
4 actions. *See* Neb. Rev. Stat. § 25-224(1). The statute of limitations "begins to run on the
5 date on which the party holding the cause of action discovers, or in the exercise of
6 reasonable diligence should have discovered, the existence of the injury or damage."
7 *Thomas v. Countryside of Hastings, Inc.*, 524 N.W.2d 311, 313 (Neb. 1994) (internal
8 quotation marks omitted). "Discovery refers to the fact that one knows of the existence of
9 an injury or damage and not that one knows who or what may have caused that injury or
10 damage." *Id.* Furthermore, a plaintiff "need not know the full extent of one's damages
11 before the limitations period begins to run, as a statute of limitations can be triggered at
12 some time before the full extent of damages is sustained." *Gordon v. Connell*, 545
13 N.W.2d 722, 726 (Neb. 1996); *see also Reinke Mfg. Co. v. Hayes*, 590 N.W.2d 380, 390
14 (Neb. 1999) ("A limitation period may begin to run even though the nature and extent of
15 the damages are not known."). Moreover, the statute of limitations begins to run even if
16 "the plaintiff may be ignorant of the existence of the cause of action." *Cavanaugh v. City*
17 *of Omaha*, 580 N.W.2d 541, 544 (Neb. 1998).

18 Here, Plaintiff's claims against Bard accrued -- and the applicable statute of
19 limitations began to run -- at the latest, on March 14, 2011. As of that date, Plaintiff
20 subjectively knew that she had been injured by her Filter. Her actions up to and on that
21 date undisputedly demonstrate Plaintiff's knowledge of her injury. Indeed, as of March
22 14, 2011, the following occurred:

- 23 • [REDACTED]
- 24 [REDACTED] (SSOF at ¶ 6);
- 25 • Plaintiff called an attorney about her potential IVC filter lawsuit after seeing
- 26 a TV advertisement soliciting potential plaintiffs. (*Id.* at ¶ 10);
- 27 • Plaintiff called her daughter to discuss her Filter. (*Id.* at ¶ 12);
- 28 • [REDACTED]

(*Id.* at ¶¶ 7, 15);

- Plaintiff's own medical records state that her filter

(*Id.* at ¶ 14);

- Plaintiff sought to have her Filter removed. (*Id.* at ¶ 13.)

Plaintiff may argue her claim did not accrue until April 7, 2011, when she had her unsuccessful removal procedure. However, as noted above, Plaintiff did not need to know the full extent of her damages before her claim accrued. *See, e.g., Seagren v. Peterson*, 407 N.W.2d 790, 792 (Neb. 1987) (“[D]iscovery does not mean the final resolution of damages; it can be triggered at some time before the full extent of the damages is sustained.”). Finally, Plaintiff may also argue that she did not know about alleged defects with her Filter, or that she had a cause of action against Bard, until sometime after March 14, 2011. But as noted above, Plaintiff did not need to know that she “has a legal right to seek redress” before her claim accrued. *See Gordon*, 545 N.W.2d at 726.

Because Plaintiff's claims against Bard accrued on or before March 14, 2011, and because Plaintiff waited until April 6, 2015, to file her lawsuit against Bard, Plaintiff's claims against Bard are time-barred by Nebraska's 4-year statute of limitations.

B. Plaintiff Should Be Judicially Estopped from Pursuing Her Claims.

Plaintiff petitioned for and received a full Chapter 7 Bankruptcy discharge in 2013, approximately two years after her claims against Bard accrued in 2011. (SSOF, ¶¶ 30, 37, 38.) Yet, when asked to identify under oath all of her property to the Bankruptcy Court, Plaintiff marked “NONE” for “contingent or unliquidated claims,” and “NONE” for “other property.” (*Id.* at ¶¶ 31, 32, 33, 35.) Plaintiff cannot reasonably dispute that she failed to identify in her Bankruptcy Petition her claims against Bard. Accordingly, her claims should be barred by the doctrine of judicial estoppel.

“Judicial estoppel is an equitable doctrine that ‘prevents a party from asserting a claim in a legal proceeding that is inconsistent with a claim taken by that party in a previous proceeding.’” *Jones v. Bob Evans Farms, Inc.*, 811 F.3d 1030, 1032 (8th Cir. 2016) (quoting *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001)). The Eighth Circuit

1 considers three factors when deciding whether to apply judicial estoppel to a party: (1) the
 2 party's later position must be "clearly inconsistent" with its prior position; (2) the party's
 3 position must have been accepted or adopted by a prior court; and (3) the party asserting
 4 inconsistent positions would derive some "unfair advantage" if not judicially stopped. *See*
 5 *Jones*, 811 F.3d at 1033. "A party who has filed for bankruptcy may be judicially
 6 estopped from pursuing a claim not disclosed in his or her bankruptcy filings." *Id.* Here,
 7 all three factors support application of judicial estoppel to bar Plaintiff's claims.

8 **First**, Plaintiff has taken inconsistent positions between her bankruptcy case and
 9 this case. She knew she had a "contingent" or "unliquidated" claim against Bard, yet she
 10 did not disclose it in her Petition. (SSOF, ¶¶ 31, 32, 33.) Even if this Court rejects Bard's
 11 statute of limitations argument and believes Plaintiff's claims against Bard accrued after
 12 March 14, 2011, at the very latest, her claims accrued on April 7, 2011, the date of her
 13 unsuccessful removal procedure. (*Id.* at ¶¶ 16, 27.) Indeed, Plaintiff admits that she first
 14 attributed her injuries to her Filter on that date. (*Id.* at ¶ 16.) And Plaintiff's decision to
 15 file her lawsuit against Bard on April 6, 2015, one day shy of the 4-year anniversary of the
 16 removal procedure strongly suggests Plaintiff's and her counsel's subjective belief that
 17 her claim accrued at least by April 7, 2011. Plaintiff's failure to disclose her claims
 18 against Bard in her Petition is tantamount to "represent[ing] to the bankruptcy court that
 19 no such claims existed." *Jones*, 811 F.3d at 1033. Of course, here, she has taken the
 20 opposite position and asserted a claim against Bard. *See id.* (asserting claims that were
 21 earlier represented as not existing "is inconsistent" with the party's prior position).

22 **Second**, the Bankruptcy Court adopted Plaintiff's position when it discharged
 23 Plaintiff's debts. *See id.* (holding that a bankruptcy court adopted the debtor's position of
 24 the lack of a claim when the court discharged the debtor's debts); *see also Van Horn v.*
 25 *Martin*, 812 F.3d 1180, 1183 (8th Cir. 2016) ("[T]he bankruptcy court adopted [the
 26 plaintiff/debtor's] representation that no claims existed when it discharged \$18,391.49 of
 27 her unsecured debt."); (SSOF, ¶ 38). Thus, the second judicial estoppel factor is met here.

28 **Third**, Plaintiff clearly derived an unfair advantage in her bankruptcy proceeding

1 by concealing her claims. Like the Eighth Circuit stated, “[i]f [Plaintiff] had disclosed
2 [her] claims, for example, the trustee could have moved the bankruptcy court to order
3 [her] to make the proceeds from any potential settlement available to [her] unsecured
4 creditors.” *Jones*, 811 F.3d at 1034; *see also Cover v. J.C. Penney Corp.*, 187 F. Supp. 3d
5 1079, 1089 (D. Minn. 2016) (holding that the third factor was met where, by failing to
6 disclose her claims in a bankruptcy proceeding, the plaintiff/debtor’s “potential damages
7 arising from this lawsuit would go directly to her and not to her creditors”).

8 Plaintiff may argue that her failure to disclose her claims against Bard in her
9 Bankruptcy Petition was inadvertent and not intended to mislead the court. But the Eighth
10 Circuit has already rejected this same argument, holding that “[a] debtor’s failure to
11 satisfy its statutory disclosure duty is ‘inadvertent’ only when, in general, the debtor either
12 lacks knowledge of the undisclosed claims or has no motive for their concealment.”
13 *Jones*, 811 F.3d at 1034 (internal citations omitted).

14 Finally, Plaintiff may recognize that she is judicially estopped from asserting her
15 claims, and she may ask this Court to allow the bankruptcy trustee to be substituted in as
16 the real party in interest. However, even if she does make such a request, this Court is not
17 obligated to allow a substitution. Where, as here, a plaintiff merely engages in “last
18 minute candor” by seeking to reopen a bankruptcy estate and having a trustee pursue her
19 claims, a trial court does not abuse its discretion in applying judicial estoppel to bar the
20 claims. *See Jones*, 811 F.3d at 1032 & 1034 (holding that the trial court did not abuse its
21 discretion in dismissing the plaintiff’s claims pursuant to the judicial estoppel doctrine,
22 where trial court concluded that the plaintiff’s “last minute candor” was not enough to
23 prevent application of the doctrine). In any event, as of the filing of this Motion, Plaintiff
24 has not sought to reopen her bankruptcy estate, (*see* SSO, ¶ 39), and the trustee has not
25 sought to intervene in this matter. The issue of trustee intervention is not ripe at this
26 moment. However, Bard notes that if the bankruptcy trustee were to seek to pursue
27 Plaintiff’s claims on behalf of her estate, any damages that could be recovered should be
28 capped at an amount sufficient to satisfy Plaintiff’s creditors and the costs and fees

1 incurred by the trustee. *See, e.g., Parker v. Wendy's Int'l, Inc.*, 365 F.3d 1268, 1273 n.4
 2 (11th Cir. 2004); *Wiggins v. Citizens Gas & Coke Util.*, No. 1:03-CV-1882-SEB-JMS,
 3 2008 WL 4530679, at *4 (S.D. Ind. Oct. 7, 2008); *Martin v. U.S. Bank*, No.
 4 4:04CV01527AGF, 2005 WL 3107722, at *6 (E.D. Mo. Nov. 18, 2005).

5 **C. The Learned Intermediary Doctrine Forecloses Plaintiff's Failure-to-Warn**
 6 **Claims (Counts II, VII) as a Matter of Law.**

7 Plaintiff's failure-to-warn claims fail because Bard provided legally adequate
 8 warnings of the complications allegedly experienced by Plaintiff to a learned
 9 intermediary, Plaintiff's implanting physician, Dr. Smith. Moreover, Dr. Smith was
 10 independently aware of the complications allegedly experienced by Plaintiff. Finally, any
 11 alleged failure to warn by Bard was not the proximate cause of Plaintiff's alleged injuries

12 In Nebraska, "[a] manufacturer or other seller is subject to liability for failing
 13 either to warn or adequately to warn about a risk or hazard inherent in the way a product is
 14 designed that is related to the intended uses as well as the reasonably foreseeable uses that
 15 may be made of the products it sells." *Rahmig v. Mosley Mach. Co.*, 412 N.W.2d 56, 72
 16 (Neb. 1987) (quoting *Prosser and Keeton on the Law of Torts, Prods. Liab.*, § 96 at 685
 17 (5th ed. 1984)). Furthermore, Nebraska has explicitly adopted the learned intermediary
 18 doctrine as stated in the *Restatement (Third) of Torts: Products Liability* § 6(d) (1997),
 19 which applies the doctrine to "[a] prescription drug or medical device." *Freeman v.*
 20 *Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 842 (Neb. 2000) (quoting *Restatement (Third)*
 21 *§ 6(d)*). Thus, a medical device manufacturer's "duty to warn extends only to members of
 22 the medical profession and not to the consumer." *Freeman*, 618 N.W.2d at 841.

23 As with other claims, to succeed on a failure-to-warn claim, a plaintiff has the
 24 burden of establishing causation. *See generally Stahlecker v. Ford Motor Co.*, 667
 25 N.W.2d 244, 253 (Neb. 2003) (discussing causation requirement in product liability
 26 cases). "[I]f a user actually knows of the danger, a failure to warn cannot be a proximate
 27 cause of the injury. " *Crook v. Farmland Indus., Inc.*, 54 F. Supp. 2d 947, 958 (D. Neb.
 28 1999); *see also Strong v. E. I. DuPont de Nemours Co.*, 667 F.2d 682, 688 (8th Cir. 1981)

1 (“If, despite deficient warnings by the manufacturer, a user is fully aware of the danger
2 which a warning would alert him or her of, then the lack of warning is not the proximate
3 cause of the injury.” (applying Nebraska law)). This same rule applies in pharmaceutical
4 drug and medical devices cases involving a learned intermediary. As the Eighth Circuit
5 Court of Appeals has recognized, “[t]he learned intermediary doctrine provides that the
6 failure of a drug manufacturer to provide the physician with an adequate warning of the
7 risks associated with a prescription product is not the proximate cause of a patient’s injury
8 if the prescribing physician had independent knowledge of the risk that the adequate
9 warnings should have communicated.” *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1137 (8th
10 Cir. 2014)⁴ (internal quotation marks omitted). Similarly, to prove proximate causation,
11 Plaintiff has the burden to prove that “a proper warning would have changed the decision
12 of the treating physician, *i.e.* that *but for* the inadequate warning, the treating physician
13 would not have used or prescribed the product.” *Ackermann v. Wyeth Pharm.*, 526 F.3d
14 203, 208 (5th Cir. 2008); *see also Ingram v. Novartis Pharm. Corp.*, 888 F. Supp. 2d
15 1241, 1246–47 (W.D. Okla. 2012) (granting summary judgment to defendant in
16 prescription drug case, where plaintiff failed to produce evidence that treating physician
17 would have changed treatment decision had a proper warning been given); *Motus v. Pfizer*
18 *Inc.*, 196 F. Supp. 2d 984, 995 (C.D. Cal. 2001) (“Pfizer may prevail in its motion for
19 summary judgment if Ms. Motus has failed to adduce evidence that Dr. Trostler would
20 have acted differently had Pfizer provided an adequate warning.”).

21 Here, the Filter is a prescription medical device not available to the general public.
22 (SSOF, ¶ 2.) Accordingly, the learned intermediary doctrine applies, and Bard only had a
23 duty to warn Dr. Smith, the physician who implanted the Filter, of the risks of the Filter’s
24 use. Dr. Smith’s testimony establishes that the warnings accompanying the Filter were
25

26 ⁴ Although the court in *Brinkley* was applying Missouri law, the basic principle that a
27 prescribing physician who has independent knowledge of the risks involved with the
28 product breaks the chain of proximate causation applies as a general proposition of law.
Indeed, the *Brinkley* court looked to and cited Arkansas and Florida law when discussing
this general rule. *See Brinkley*, 772 F.3d at 1137.

adequate to warn him of the specific complications encountered by Ms. Kruse. Dr. Smith testified that before he placed the Filter, he had the IFU that accompanied the Filter available to him to read. (*Id.* at ¶ 17.) The relevant IFU contains specific warnings regarding the risks of filter tilt, migration, fracture, perforation, and inability to retrieve, which are complications allegedly experienced by Ms. Kruse. (*Id.* at ¶ 18.) Under the bolded heading “**Potential Complications**,” the IFU reads as follows:

- Movement or migration of the filter is a known complication of vena cava filters.
- Filter fracture is a known complication of vena cava filters.
- Perforation or other acute or chronic damage of the IVC wall.

* * *

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.

(*Id.* at ¶ 19.a) (emphasis in original). Additionally, in the bolded “**Clinical Experience**” section, the IFU notes that in the clinical trial regarding the G2 Filter, “filter tilt” was observed 15 times, and that there were “3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone® Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall.” (*Id.* at ¶ 19.b) (emphasis in original). Finally, under the bolded “**G2® Filter Removal**” heading, the IFU states in bolded language as follows:

It is possible that complications such as those described in the “Warnings”, “Precautions,” and “Potential Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.

(*Id.* at ¶ 19.c) (emphasis in original). Because the IFU warned Dr. Smith regarding the relevant risks of using the Filter, Bard’s warnings were legally adequate.⁵

⁵ Plaintiff may argue that Bard failed to warn Dr. Smith of the relative complication rates

1 In addition, Plaintiff has not established that any failure to warn by Bard was the
2 proximate cause of her injuries. Dr. Smith testified he was independently aware of the
3 risks of IVC filter tilt, migration, perforation, and fracture before he decided to use the
4 Filter. (*Id.* at ¶ 20.) Additionally, although Dr. Smith testified on occasion that he may
5 have wanted to know certain alleged factual information presented by Plaintiff's counsel,
6 and that more information is helpful, (*see id.* at ¶ 21), he never testified that had he
7 received some additional information from Bard, he would have used a different device
8 with Plaintiff. (*Id.* at ¶ 22.) At most, he testified "it's possible" he would have changed his
9 treatment of Plaintiff. (*Id.* at ¶ 23.) Finally, when asked whether the alleged facts and
10 documents shown to Dr. Smith by Plaintiff's counsel would have changed his decision to
11 use a G2 Filter with Ms. Kruse, Dr. Smith admitted that he "wouldn't want to say how
12 they would influence me without knowing what they say in detail." (*Id.* at ¶ 24.)

13 In the absence of evidence establishing that a failure to warn was the proximate
14 cause of Plaintiff's injury -- that is, that a different warning would have caused Dr. Smith
15 to choose a different product -- Plaintiff's failure-to-warn claims fail as a matter of law.

16 **D. Plaintiff's Negligent Post-Sale Duty to Warn Claim (Count VI) Fails as a**
17 **Matter of Law Because Nebraska Does Not Recognize Such a Claim.**

18 No court applying Nebraska law has recognized a post-sale duty to warn or retrofit.
19 Instead, the Eighth Circuit has stated that "Nebraska would not impose either a post-sale
20 duty to warn or a duty to retrofit." *Anderson v. Nissan Motor Co.*, 139 F.3d 599, 602 (8th
21 Cir. 1998). The *Anderson* court based its opinion on the Nebraska Supreme Court decision
22 in *Rahmig v. Mosley Mach. Co.*, 412 N.W.2d 56 (Neb. 1987). *See Anderson*, 139 F.3d at
23 602. In *Rahmig*, the Nebraska Supreme Court held that a plaintiff is not required to prove

24 of Bard's IVC filters compared to competitor devices. Such an argument would be
25 misplaced. Under Nebraska law, a manufacturer has a duty to warn of "risk or hazard
26 inherent in the way *a product* is designed," not to provide a warning regarding some other
27 product. *See Freeman*, 618 N.W.2d at 841 (emphasis added) (internal quotation marks
28 omitted). For the reasons and arguments stated at footnote 3, page 9 of Bard's Motion for
Summary Judgment filed in *Jones v. C. R. Bard, Inc., et al.*, which are incorporated herein
by reference, Bard had no legal duty to provide warnings to Dr. Smith regarding the rates
of complications with the G2 Filter in comparison to any other product.

1 a feasible alternative safer design in a negligent design case, reasoning that to hold
 2 otherwise “unnecessarily invites perilous and unfairly prejudicial evidence of postaccident
 3 matters excludable under Neb. Evid. R. 407.” *Rahmig*, 412 N.W.2d at 82. In dicta, the
 4 court also stated that “[i]n a products liability action, the plaintiff has the burden to prove
 5 that the alleged defect *existed when the product left the manufacturer.*” *Id.* at 69 (as
 6 quoted in *Anderson*, 139 F.3d at 602 (emphasis added by *Anderson* court)). The *Anderson*
 7 court reasoned that “[t]he Nebraska Supreme Court’s statements in *Rahmig* lead us to
 8 conclude that Nebraska favors limiting the state’s products liability law to actions or
 9 omissions which occur at the time of manufacture or sale.” *Anderson*, 139 F.3d at 602.
 10 Accordingly, the *Anderson* court affirmed the district court’s decision to dismiss the
 11 plaintiff’s post-sale duty to warn and retrofit claims pursuant to Rule 12(b)(6).

12 Because no Nebraska court has ever recognized a post-sale duty to warn or retrofit
 13 -- and because such a claim runs contrary to Nebraska Supreme Court’s statements and
 14 reasoning in *Rahmig* -- this Court should decline to recognize such a claim here.

15 **E. Plaintiff’s Negligence Per Se Claim (Count IX) Cannot Be Based on**
 16 **Alleged Violations of a Statute or Regulation.**

17 Plaintiff’s negligence per se claim fails as a matter of clear Nebraska law. The
 18 Nebraska Supreme Court recently stated “that the violation of a regulation or statute is not
 19 negligence per se, but may be evidence of negligence to be considered with all the other
 20 evidence in the case.” *Scheele v. Rains*, 874 N.W.2d 867, 872 (Neb. 2016); *see also In re*
 21 *Derailment Cases*, 416 F.3d 787, 795 (8th Cir. 2005) (affirming dismissal of negligence
 22 per se claims because “violation of a regulation or statute is generally not recognized as
 23 negligence per se under Nebraska law”).

24 Here, Plaintiff’s negligence per se claim (Count IX) is based exclusively on alleged
 25 violations of federal statutes and federal regulations. (*See* Master Complaint for Damages
 26 for Individual Claims [Dkt. No. 364] at ¶¶ 229-234.) Under clear Nebraska law, such
 27 alleged violations cannot form the basis of a negligence per se claim. Accordingly,
 28 Plaintiff’s negligence per se claim fails as a matter of law.

F. Plaintiff's Negligent and Fraudulent Misrepresentation/Concealment Claims (Counts VIII, XII, XIII) Fail as a Matter of Law Because Plaintiff Cannot Prove the Essential Element of Reliance.

Reliance is an essential element of any negligent or fraudulent misrepresentation or concealment claim. *See Knights of Columbus Council 3152 v. KFS BD, Inc.*, 791 N.W.2d 317, 330-31 (Neb. 2010). Before a plaintiff can prove reliance, he or she “must have received the information” that allegedly was misrepresented by the defendant. *Id.* at 328. Accordingly, “plaintiffs cannot show reliance on a misrepresentation that never reached them and of which they had no knowledge.” *Id.* Likewise, for a plaintiff to succeed on a concealment claim, the plaintiff must have first received some representation. *Id.* (“[A] plaintiff must have received the representation before the plaintiff can show that a defendant had a duty to disclose additional facts [to support a concealment claim].”).

Here, Plaintiff’s misrepresentation and concealment claims fail because she cannot prove the essential element of reliance. Ms. Kruse testified that she never spoke to anyone at Bard. (SSOF, ¶ 40.) She never received any written or verbal information about her filter before she received it. (*Id.* at ¶ 41.) She testified that she never researched IVC filters. (*Id.* at ¶ 42.) Finally, she testified that she did not even know that Bard was the manufacturer of her filter until the day she underwent her unsuccessful retrieval procedure. (*Id.* at ¶ 43.) Accordingly, the undisputed evidence demonstrates that Ms. Kruse did not receive any representation from Bard, and, thus, could not, as a matter of law, have relied on any alleged misrepresentation.

Additionally, Bard submits that whether Plaintiff’s implanting physician relied on an alleged misrepresentation or omission should be irrelevant for purposes of Plaintiff’s misrepresentation and concealment claims. However, even if his actions were relevant, Dr. Smith testified he relies on his training, experience, the experience of his colleagues, and the applicable medical literature when he makes treatment decisions regarding his patients, including Ms. Kruse. (*Id.* at ¶ 25.) He ***did not*** testify he relied on any statement by Bard -- or any omission of material fact -- in deciding to use the Filter. (*Id.* at ¶ 26.)

Neither Plaintiff nor her implanting physician testified that they relied on a material

misrepresentation -- or omission of material fact -- when deciding to use a Bard G2 Filter. Because Plaintiff cannot prove the essential element of reliance, her misrepresentation and concealment claims fail as a matter of law.

G. Plaintiff’s Consumer Fraud Claim (Count XIV) Fails Because the Relevant Statute Awards Only Injunctive Relief, and Because the Statute Applies Only to Claims Based on Alleged Losses of Business or Property.

Nebraska has adopted the Uniform Deceptive Trade Practices Act (“UDTPA”), under Neb. Rev. Stat. § 87-301, *et seq.*, and the Consumer Protection Act (“CPA”), under Neb. Rev. Stat. § 59-1601, *et seq.* As a matter of law, Plaintiff cannot sustain her personal injury action against Bard based on alleged violations of those Acts.

Regarding the UDTPA, although it allows for private causes of action, the Act is explicitly limited to actions for injunctive relief. *See* Neb. Rev. Stat. § 87-303(a) (“A person likely to be damaged by a deceptive trade practice of another may bring an action for, and the court may grant, *an injunction* under the principles of equity against the person committing the deceptive trade practice.” (emphasis added)). As the Nebraska Supreme Court has stated, “by its own terms, § 87–303(a) only provides for equitable relief consistent with general principles of equity.” *Sid Dillon Chevrolet-Oldsmobile-Pontiac, Inc. v. Sullivan*, 559 N.W.2d 740, 746 (Neb. 1997). The Nebraska UDTPA “does not provide a private right of action for damages.” *Vallejo v. Amgen, Inc.*, No. 8:14CV50, 2014 WL 4922901, at *5 (D. Neb. Sept. 29, 2014). Here, Plaintiff seeks monetary damages, not injunctive relief. (*See* Master Complaint [Dkt. No. 364] at “Prayer for Relief.”) Accordingly, Plaintiff’s UDTPA claim fails.⁶

With respect to the CPA, although the Act allows for private causes of action, the Act is explicitly limited to instances where a person “is injured in his or her business or property.” Neb. Rev. Stat. § 59-1609. By its express terms, the CPA does not create a cause of action for personal injury claims. Here, Plaintiff’s claim is for personal injury, not injury to her “business or property.” Therefore, Plaintiff’s personal injury product

⁶ Plaintiff also failed to comply with the notice requirements under § 87-303.12.

liability claim cannot be based on alleged violations of the CPA. Finally, while the CPA bars various forms of trade or business practices -- such as unfair competition, monopolies, conspiracies in restraint of trade -- Plaintiff has never identified an alleged violation by Bard of one of the prohibited practices under the Act. Accordingly, Plaintiff's CPA claim fails as a matter of law.

H. Plaintiff's Claim for Punitive Damages Fails as a Matter of Law Because Nebraska Does Not Permit Recovery of Punitive Damages in a Civil Case.⁷

"It is a fundamental rule of law in [Nebraska] that punitive, vindictive, or exemplary damages are not allowed. The measure of recovery in all civil cases is compensation for the injury sustained." *Miller v. Kingsley*, 230 N.W.2d 472, 474 (Neb. 1975); *see Distinctive Printing & Pkg. Co. v. Cox*, 443 N.W.2d 566, 574 (Neb. 1989) ("[P]unitive, vindictive, or exemplary damages contravene Neb. Const. art. VII, § 5, and thus are not allowed in this jurisdiction."). In light of Nebraska's "[c]lear constitutional prohibition" against punitive damages, *Enron Corp.*, 940 F.2d at 313, the Court should grant summary judgment on Plaintiff's punitive damages claim. *See Sanford v. Ektelon/Prince Sports Grp., Inc.*, No. 8:97CV368, 1999 WL 33537914, at *5 (D. Neb. Nov. 5, 1999) (granting summary judgment in light of Nebraska's "clear mandate" against punitive damages).

V. Conclusion.

For these reasons, Bard respectfully requests that this Court grant Bard's Motion for Summary Judgment.

⁷ Because the parties agree that Nebraska substantive law applies, the Court need not engage in a conflict-of-law analysis here. Nonetheless, even when faced with conflict-of-law issues, courts overwhelmingly defer to Nebraska's "strong public policy interest in prohibiting punitive damages." *Kammerer v. Wyeth*, No. 8:04CV196, 2011 WL 5237754, at *5 (D. Neb. Nov. 1, 2011); *see also Enron Corp. v. Lawyers Title Ins. Corp.*, 940 F.2d 307, 313 (8th Cir. 1991) ("[B]alancing Nebraska's clear constitutional prohibition against the Virgin Islands' adoption of the Restatement's position, we conclude that Nebraska has the most significant relationship to this case with respect to the issue of punitive damages."); *Bamford, Inc. v. Regent Ins. Co.*, No. 8:13CV200, 2014 WL 12539650, at *3 (D. Neb. June 12, 2014) ("Wisconsin's interest to punish its business-tortfeasors does not overcome Nebraska's most significant relationship and forum-court presumption.").

1 RESPECTFULLY SUBMITTED this 28th day of August, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

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